**REMARKS**

Claims 96-143 are pending in this application. It was noted that two claims 48 were pending in this application. Accordingly, by this Amendment, claims 48-95 have been cancelled and replaced by claims 96-143.

The drawings have also been amended to provide formal drawings, and to address informalities identified by the Examiner in the January 9, 2008 Office Action for the continuation application (11/680,942) to the instant application. The specification has also been amended to clarify paragraphs [0033], [0074], [0080], and [00104] and to address informalities identified in the continuation application. The originally-filed application supports the amendments by at least paragraphs [0025] and [0065], and by Figs. 1, 2, 11a, 12, 14a, and 15. The title has also been amended.

The amendments to the drawings and specification do not add new matter.

Prosecution on the merits is requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, Applicant respectfully requests consideration of this Application and the prompt allowance of at least the pending claims.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the undersigned to expedite prosecution of the application.

The Commissioner is hereby authorized by this paper to charge any fees during the entire pendency of this application including fees due under 37 C.F.R. §§ 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-3840. **This paragraph is intended to be a CONSTRUCTIVE PETITION FOR EXTENSION OF TIME in accordance with 37 C.F.R. § 1.136(a)(3).**

Respectfully submitted,

Steven W. Allis
Attorney for Applicants
Reg. No.: 50,532

Date: May 9, 2008

Patent Administrator
**Proskauer Rose LLP**
1001 Pennsylvania Avenue, NW
Suite 400 South
Washington, DC 20004
Telephone: 202.416.6800
Facsimile: 202.416.6899

**CUSTOMER NO: 61263**

Attached:

**ATTACHMENT 1**

**ATTACHMENT 2**

**REPLACEMENT SHEETS (FIGS. 1-21)**

**ATTACHMENT 1**

Please replace paragraphs [0001], [0007], [0016], [0019], [0022], [0027]-[0028], [0033], [0035]-[0036], [0063], [0070]-[0072], [0074], [0080], [0085], [0088], [0092], [0096]-[0097], [00101], and [00103]-[00108] with the amended paragraphs provided below:

**[0001]** This is a national stage application under 35 USC § 371 of International Application PCT/DE03/00844, filed on March 17, 2003, which claims priority to DE20204363.0, filed March 19, 2002, DE20204362.2, filed March 19, 2002, DE20204361.4, filed March 19, 2002, DE10212156.7, filed March 19, 2002, DE10212139.7, filed March 19, 2002, DE10212155.9, filed March 19, 2002, DE20209525.8, filed June 19, 2002, DE20209530.4, filed June 19, 2002, DE20211934.3, filed August 2, 2002, and DE20215962.0, filed October 17, 2002, the entireties of which are hereby incorporated by reference.

**[0007]** On the other hand, the biopsy needle arrangement described in International Publication No. WO 98/25522 enables a spring-operated relative motion between the hollow biopsy needle, located on the interior, and the outer hollow needle surrounding the biopsy needle. In this case as well, the biopsy needle is positioned distally to the sharpened distal tip of the hollow needle in order to take a sample, there being provided a partial vacuum source for supplying a partial vacuum through the hollow biopsy needle into the area of its recess, assisting the process of bringing in the tissue. The process of positioning the biopsy needle relatively and finally inside the region of tissue being investigated is done exclusively manually. Such a positioning leads only to unsatisfactory biopsy results, especially when investigating hard tissue regions.

**[0016]** The locking of the tension slide has a double-arm lever, whose one arm engages under spring pressure with the recess of the tension slide. In order to allow for use of the tension device for different biopsy needles with different insertion depths, *e.g.*, 15 to 25 mm, it is only necessary to adapt the length of the engaging lever and use appropriate settings in the electronics, for example. The plastic piece joined to the biopsy needle enables a turning of the sample removal chamber by means of a knurled disk. The biopsy needle can be locked in the desired position by the interaction of the polygon of the plastic piece and the biopsy needle carrier. A

notch made in the knurled disk shows the user the radial position for the opening of the sample removal chamber.

**[0019]** The storing of the biopsy needle/cutting sheath in a biopsy needle carrier made of plastic has the advantage, among others, that the molded-on sliding surfaces enable a trouble-free sliding on the opposing surfaces of the base block and the molded-on block. The biopsy needle carrier transmits the forces from the spindle drive of the cutting sheath to the tension slide. Since the spindle drive thrusts against the holder of the base block when the tension slide changes position and it can slide freely when the tension sheath is rotated (the gear can slide axially in the toothed roller), the drive unit can be used for both motion sequences (tensioning of the tension slide, opening and closing of the sample removal chamber by means of the cutting sheath). The miniature switch integrated in the housing end piece, which turns the power supply off and on by the closing of the housing cover with the vacuum pressure-generating device inserted, as well as the retaining tabs arranged on the biopsy needle carrier, are safety mechanisms which prevent a tensioning of the tension slide when the housing cover is open. Furthermore, an opening of the housing cover when the needle is under tension will be precluded.

**[0022]** When using a coaxial cannula in which the needle unit is inserted, so as to achieve an exact positioning, for example, one must make sure that no air can get in between the outer circumference of the needle and the inside of the coaxial cannula when a vacuum is produced. Therefore, a seal element is provided at the proximal side of the coaxial cannula tube. Since the depth of insertion of the needle unit is dictated by the cocking distance of the tension slide, unless means are provided in the hand piece for different depths of insertion, the use of spacing pieces between the coaxial cannula and guide roller has proven to be especially advantageous. The spacing piece is strung onto the needle unit and sits distally on the proximal end of the coaxial cannula, and proximally on a guide roller arranged in the hand piece. As a result, for the same insertion length dictated by the device, the depth of penetration is reduced by the length of the spacing piece, resulting in easier production conditions.

**[0027]** Figure 4 shows a cross section A-A in Figure 3 (left housing part).

**[0028]** Figure 5 shows a cross section B-B in Figure 3 (right housing part).

**[0033]** Figure 9a shows a unit of the biopsy device that is fixed to the housing (without housing cover or bottom) in the uncocked condition.

**[0035]** Figure 10a is the same as Figure 9a, but tension slide in cocked position.

**[0036]** Figure 10b is the same as Figure 9b, but in locked condition.

**[0063]** The cocking device (situated right front) itself consists of a tension slide 28, placed on a bolt 30, the bolt screwing into the base block 8. The bolt 30 has a spiral spring 31 surrounding it. The locking device (see especially Figures 9b and 10b) of the tension slide is secured to the block 26. In the top, rear, right interior of the housing is accommodated the vacuum pressure-generating device 5 with parts of the actuator; the actuating motor with reduction gearing for the vacuum pressure-generating device is located in the left, bottom, rear area of the housing interior.

**[0070]** A perspective representation of the base block 8 (looking from the front in the direction of the X-axis) is shown by Figure 8a; the base block 8 is shown from the rear in the X-axis by Figure 8b (both of them perspective views). The base block 8 can be divided into two halves, looking in the lengthwise direction; the front part serves to secure the joint actuation for cutting the sheath and tension slide, and also in its upper part to mount the biopsy needle carrier (Figure 8a); the rear part serves to secure the actuation for the vacuum pressure-generating device and to mount one side of the vacuum pressure-generating device (Figure 8b). Between the two actuating motors 21, 58, beneath the center rib 87, is arranged a central electronic board. The base block 8 has in its left front part a U-shaped space 24, in which is installed a toothed roller 23, driven by the gear motor 21. For this, the take-off shaft of the gear motor is mounted or inserted in an opening in the wall 25 of the base block 8. The toothed roller 23 is mounted on the take-off shaft and secured to it, for example, by means of a screw, so that it cannot turn or shift. At the other end, the toothed roller 23 is mounted in the wall 22 of the base block 8. The actuating motor used is a DC motor with a speed of around 11000 rpm. The DC motor is connected to a planet gear with high reduction ratio, on whose take-off shaft the toothed roller 23 is mounted.

**[0071]** An additional block 26 is molded on the wall 22, pointing to the right, which accommodates both the swiveling double lever 33 for the locking process and also serves to fasten the bolt 30 for guiding the tension slide 28. The bolt 30 is screwed into the threaded borehole 29. During the cocking process, the tension slide 28 moves to the right on the bolt 30 and the separating plate 114 is arranged underneath. The spiral spring 31 arranged on the threaded bolt 30 is compressed during the cocking process. At one end, the spiral spring thrusts against an end piece 32 of the threaded bolt or directly against the end cover 7 of the housing; the

other end of the spiral spring thrusts against the end of the guide borehole 115 of the tension slide.

**[0072]** The tension slide 28 moves on the threaded bolt and the separating plate 114 and is thus prevented from twisting. One arm 99 of the double-arm lever 33 of the locking device engages with a groove 27 of the tension slide 28 (Figures 9a and 10a). The locking device, integrated in the block 26 of the base block 8, consists of the double-arm lever 33, which can swivel about an upright axis 35 (looking in the Y-axis) by means of a compression spring 34. The axis 35, an upright pin, is secured in the boreholes 38 of the base block. In the uncocked condition, the part 99 of the double-arm lever lies in the groove 27 of the tension slide; the compressed spring 34 acts on the part 100 of the lever to press the locking button 88 outward (forward). As soon as the part 99 of the double-arm lever can engage in the recess 82 of the tension slide, the activating button 88 is pressed outward. The tension slide is locked by the locking of the lever part 99 in the cocked condition and can now be triggered when necessary with the activating button 88. Since the tension slide is advisedly made of plastic, it has proven advisable to employ a metal part 83 in the recess, so as not to damage the plastic, since the double-arm lever is made of metal. Unlike the removable element 20, the hand piece 1 with replaced insertion element can be used repeatedly. The cocking distance corresponds to the depth of penetration of the biopsy needle into the tissue. Hence, the length of the lever 99 likewise corresponds to the cocking distance. Since the depth of penetration is generally between 15 and 25 mm, the same hand piece 1 can be used for different depth of penetration by appropriately configuring the length of the lever 99 and changing the setpoints of the control system.

**[0074]** Above the U-shaped space 24 for the toothed roller 23, at the height of the sliding surface 42, the basic block 8 has a U-shaped upwardly open holder 36, for inserting the biopsy needle/cutting sheath among other things. This holder serves primarily as a radial thrust bearing, i.e., as a prop for the actuating part connected to the cutting sheath, the gear 74, or the plastic disk 78, in order to bring the tension slide into its cocked position by means of the actuating device 106, as shall be described afterwards. In the upper rear part of the base block there is provided another U-shaped insert element 62, in which the free end 61 of the threaded spindle of the vacuum pressure-generating device 5 is inserted. In the middle, top, of the base block 8 is the recess 45, into which the dog 12 of the locking latch 11 of the housing cover is forced. A

cover 46 arranged on the base block 8, pointing to the left, separates the space of the actuating motors and the board from the upper left part of the housing interior, which is used primarily to keep the exchangeable biopsy needle carrier 37, including biopsy needle and cutting sheath. The cover 46 protects the electric gear motors and the board against dirt. The board for the electronics lies between the actuating motors and underneath the middle rib.

**[0080]** Details of the sample removal chamber and the tip of the biopsy needle are represented in Figures 11a-11e. The sample removal chamber 71 adjoining the needle tip 70 is open from above for approximately 25% of its cross section. The cutting edges can be ground or sharpened. The sample removal chamber is between approximately 15 and 25 mm in length. It adjoins the cavity of the biopsy needle. At the transition, ie., the right end of the sample removal chamber, the cross section of the cavity of the biopsy needle is closed between approximately 50% and 75% by a narrowing, e.g., a stopper 79 (Figures 11b-11e). The height of the stopper is chosen such that it extends downward past the recess of the sample removal chamber. In this way, the vacuum will especially draw in the tissue sample through the continuous opening of the sample removal chamber and bring the tissue sample up against the wall of the sample removal chamber.

**[0085]** The plunger 54 is configured in familiar fashion as a syringe plunger. The syringe body made from plastic, being a cylinder with a bottom, is transparent. In order to prevent a twisting of the threaded spindle 53 upon actuation of the threaded spindle nut, the two opposite surfaces 60 of the threaded spindle are planar in configuration (Figure 14d). The threaded spindle is inserted into the insert element by its free end. The spacing between the surfaces of the threaded spindle corresponds to the width of the U-shaped insert element 62 of the base block 8. There is only slight play between the U-shaped cross section of the insert element and the spindle surfaces at either end. The threaded spindle nut thrusts against the base block. In order to prevent the syringe body 52 from sliding out upon turning of the threaded spindle nut, the bearing surface at the base block 8 is slightly conical toward the bottom. The connection piece 63 of the syringe body 52 is inserted into the passage 16 of the right end cover 7 so that the syringe body is held in roughly horizontal position.

**[0088]** The handling of the biopsy mechanism shall now be explained more fully. The removable insert element 20, comprising a vacuum pressure-generating device, elastic connection element, biopsy needle carrier with needle and cutting sheath and additional elements

connected to it, also contains a guide roller 81 mounted on the needle. This unit, including an insert aid, comes in a sterile package. The plunger 54 in the syringe body 52 comes slightly (1-2 mm) lifted up from the syringe bottom, the sample removal chamber 71 of the biopsy needle 2 is open so that one can make a visual inspection of the chamber prior to inserting. After opening the housing cover 10, the carrier element 37, including biopsy needle 2, cutting mechanism 3, and other parts connected with it, such as the vacuum pressure-generating device 5 hooked up to the connection element 4, is inserted into the connection element provided for this (Figure 2).

**[0092]** After the starting positions are reached for the vacuum pressure-generating device and the biopsy needle/cutting sheath, the cocking diode 94 and the sample removal diode 92 light up green, and the reset diode goes out. The operator must now decide whether to initiate the cocking of the tension slide or to remove an additional sample, e.g., because he has already previously removed one tissue sample. If the operator presses the cocking button 90, the cocking of the tension slide is initiated; the cocking diode blinks green, the sample removal diode 92 goes out. By pressing the cocking button, the electrical DC gear motor 21 receives current and the DC gear motor actuates the toothed roller 23. The gear 74 meshing with the toothed roller 23 turns the spindle shaft and at the same time the cutting sheath 3 connected to it. Since the spindle nut 75 is press-fitted in the biopsy needle carrier 37 and the gear 74 is supported by the plastic disk 78 against the holder 36, which is firmly connected to the housing by the base block 8, the turning of the threaded spindle casing 73 has the effect of moving the biopsy needle carrier to the right.

**[0096]** It has proven to be advantageous to direct the partial vacuum by the stopper 79 primarily at the lower region, the lower side, of the sample removal chamber, and the stopper 79 will prevent or impede tissue from getting into the biopsy hollow needle. When the sample removal chamber is fully open--the tissue sample is accommodated in the sample removal chamber--the gear motor 21 is reversed and the sample removal chamber is closed. By turning the cutting sheath, the tissue is separated by the cutting edge 72 of the sheath 3 during the closing process. In order to reliably cut through the tissue filaments, it is advantageous to move the cutting sheath 3 beyond the distal end of the sample removal chamber (around 2 mm). In order to accomplish this, it is only necessary to program accordingly the microprocessor where the control data is kept. Because of the special configuration of the sample removal chamber and thanks to the vacuum applied, the tissue sample is held in the chamber without torsion, so that

the tissue sample is not twisted or turned by the rotating and lengthwise moveable cutting sheath 3 which surrounds the biopsy needle on the outside, as described.

**[0097]** After the sample removal chamber is closed, the DC gear motor is activated for the vacuum generating unit 5. The plunger 54 is first retracted far enough to clear the ventilation opening (Figure 14c). After the vacuum is dissipated in the system, the plunger travels toward the vacuum bottom until the ventilation borehole is again closed, in order to prevent the outflow of bodily fluid (cytological fluid). The blinking of the sample removal diode 92 goes out. The ejection diode 93 lights up green. The biopsy needle with closed sample chamber is extracted from the cannula. After the removal of the biopsy unit and providing a vessel to receive the tissue sample and fluid, the program button 89 is again operated and the ejection diode 93 starts to blink. At first, the gear motor 21 of the cutting sheath is operated to open the sample removal chamber roughly halfway. After this, the DC gear motor 58 of the vacuum pressure-generating device is activated. The turning direction of the DC gear motor 58 remains and the threaded spindle 53 with plunger moves in the direction of the syringe bottom, so that now an excess pressure is created in the system. The plunger travels up to the plunger bottom, and the actuating motor 58 is deactivated.

**[00101]** After completion of the biopsy, the interchangeable element 20 (vacuum/pressure device, biopsy needle/cutting device with all elements arranged on it) is removed from the top after releasing the cover. To make it impossible to open the housing when the tension slide is cocked, a safety tab 84 is arranged on the biopsy needle carrier, which bears against the left end surface 85 of the closure mechanism in the cocked condition. In this way, the closure mechanism, moveable in the X-axis, can no longer be moved to the left into the open position and thus the dog 12 can no longer be taken out from the recess 45. On the other hand, the housing cover also cannot be closed if the carrier unit has been inserted in the cocked condition, since the safety tab prevents the latch from being introduced into its designated space. The surface 85 of the latch adjoins the safety tab. The battery charge diode 96 is turned off as soon as the housing cover is- opened. When the cover is closed and the insert element 20 is installed, the battery charge diode indicates whether sufficient energy is available.

**[00103]** Basically, there are two conceivable methods for detecting the actual values and comparing them to the nominal values. One method is based on measuring the lengthwise displacement of the threaded spindle as it is pulled out or pushed in, and measuring the axial

displacement of the cutting sheath or the biopsy needle carrier. In order to detect these changes, photocells or miniature switches are arranged inside the housing, in particular on the extension of the base block 8. In addition, a positioning finger 103 is mounted on the cutting sheath, while the free end 61 protruding from the plunger unit can be used as a measuring point for the threaded spindle of the vacuum pressure-generating device; if the front edge of the biopsy needle carrier is used as a measuring point with a photocell, no additional positioning finger is required. The embedded photocells are covered with suitable transparent material in case of possible contamination. The positioning finger 103 engages with a slot in the biopsy needle holder. At appropriate places on the extension of the base block 8 there are provided recesses 107, in which photocells or miniature switches are installed, which interact either with the free end 61 of the plunger spindle, the positioning finger 103, or an edge of the biopsy needle carrier (see Figure 15). These signals (actual value) are processed in the electronics to form the control signals.

**[00104]** The other system is based on measuring the number of revolutions of the DC motors. In this case, a pickup is mounted on the shaft of the DC motor, which interacts with a photocell mounted on the housing of the DC motor. In this way, the number of revolutions of the motor is measured. Since the DC motors operate with a speed of around 10,000 to 12,000 rpm, depending on the load, and on the other hand the secondary planet transmission arranged at the take-off end which interacts with the spindle drive considerably reduces the number of revolutions, an exact lengthwise control is possible. The lengthwise displacement by the spindle drive is a constant value proportional to the operating speed and is therefore sufficient as a control signal for the lengthwise displacement. In order to precisely determine the position of the cutting sheath 3 as well as the plunger 54 at the start, i.e., after inserting the removable element and closing the housing cover 10, the DC gear motor 58 rotates the plunger 54 until it strikes against the syringe bottom and the DC gear motor 21 brings the drive of the cutting sheath to a zero position by moving the gear 74 until it strikes against the threaded spindle nut 75. (The threaded spindle nut 75 abuts against the gear 74.) From this zero position, the individual steps are then controlled by comparing the settings and the actual values. The necessary cables from the measuring pickup to the electronics are accommodated in the housing, as is the board with the electronic components. A microprocessor arranged inside the housing, under the cover, with the setpoint values stored in it, controls the individual processes.

**[00105]** In order to enable easy insertion of the removable insert unit, the insert aid shown in Figures 16 and 17 can be used. As Figures 16 and 17 show in particular, the biopsy needle carrier is enclosed by two brackets 108 and axially fixed in the holder by an additional cross piece 109, so that it comes to lie parallel to the vacuum/pressure device in the insert aid. The vacuum pressure-generating device is likewise enclosed by the bracket 116 at one side and by the centrally arranged bracket 108 on the other side. In addition, a pin 110 engages with the ventilation borehole 67. This ensures that the vacuum pressure-generating device is oriented parallel to the biopsy needle carrier (Figure 1). The parts so oriented are fixed in the insert aid so that they can easily be inserted from above into the hand piece 1 by means of the holder piece 117. Since the parts come in a sterile package with the insert aid, the interchangeable element 20 can be removed from the package without manual contact and be inserted in a sterile manner into the hand piece 1. The brackets are slightly slanted for easier lodging of the vacuum pressure-generating device and the biopsy needle carrier. Since the insert aid is made of plastic, the installed parts can easily be held in place by clamping, thanks to appropriate choice of the tolerance and flexibility.

**[00106]** The tip of the needle unit of the biopsy device can be placed directly on the tissue being sampled and inserted into the tissue. It can be expedient, however, to first position a coaxial cannula and then introduce the portion of the needle unit (consisting of biopsy needle and cutting sheath) protruding from the hand piece I of the biopsy device into the coaxial cannula 125. In this case, one should make sure that, when the vacuum is created for sucking in the tissue sample, no air can get in from the outside into the space between the inner surface of the coaxial cannula and the outer surface of the needle unit. In the coaxial cannula (Figure 18) consisting of a tube 121 with cap 122 placed at the proximal end, the tube 121 at the proximal end has a seal element 123 (e.g., a properly dimensioned silicone hose), into which the needle unit is placed. In order to insert the coaxial cannula, a spike 124 is connected to the coaxial cannula 125. The spike 124 has a tip 126 protruding beyond the distal end of the coaxial cannula in the inserting state. The connection between coaxial cannula and spike is a screw fastening, for example, so that the spike cap is configured as a screw cap 127. The screw cap is screwed onto the proximal end of the cap 122. The tube of the coaxial cannula is held in the cap 122 by clamping, for example. After inserting the coaxial cannula, the spike is removed and the needle unit of the biopsy device (in the cocked condition) is introduced and positioned in the coaxial

cannula (Figure 20). The distal flank 101 of the guide roller is placed on the proximal end surface 128 of the cap. After the tension slide is released, the needle tip with the sample removal chamber is forced into the tissue to its full length.

**[00107]** The depth of penetration of the biopsy needle unit of the biopsy device is between 20 and 35 mm, depending on the selected size of needle. In general, it is 20 mm. In the case of small breasts or tumors lying just below the skin, the depth of penetration of the biopsy needle is therefore too deep, since the biopsy device is placed directly or by means of the guide roller onto the coaxial cannula and the depth of penetration cannot be changed at the device. The depth of penetration is device-fixed. In order to be able to use the same biopsy device with the same biopsy needle and same depth of insertion and the same, i.e., uniform coaxial cannula with same overall length and less depth of insertion, one or more spacing pieces 129 are placed medially onto the biopsy needle prior to insertion; thus, these lie medially in front of the guide roller mounted in the housing and the proximal end surface 128 of the cap 122. Thus, by introducing spacing pieces or a spacing piece, the depth of penetration can be changed for the same depth of insertion provided in the device.

**[00108]** After inserting the spacing piece, the tip of the biopsy needle in the cocked condition no longer projects slightly from the coaxial cannula, as when no spacing piece is used, but rather lies in the coaxial cannula. The depth of penetration is thus reduced by the length L of the spacing piece (also see Figures 20 and 21). This does not impair the functioning of the sample removal chamber or the operation of the cutting sheath. For example, if a spacing piece of 10 mm is used with a depth of needle penetration of 20 mm, the depth of penetration will be reduced to 10 mm. Of course, the spacing piece can be made up of one or more parts, i.e., when using spacing pieces of 5 mm thickness, two spacing pieces are necessary to reduce the depth of penetration by 10 mm. The adding of spacing pieces or one spacing piece of corresponding length offers the possibility of using a uniform coaxial cannula including a uniformly added insertion spike 124 for various depths of penetration. The same result regarding a reduced depth of penetration could also be achieved by using caps of different height or by mounting the spacing pieces on the cap, which is equivalent to the threaded-on spacing pieces.

Please replace the section entitled "List of parts" beginning at page 35 with the amended text provided below:

List of parts

1 hand piece

2 biopsy needle

3 cutting sheath

4 connection element

5 vacuum pressure-generating device

6 housing end cover (left)

7 housing end cover (right)

8 base block

9 housing lower piece

10 housing cover

11 locking latch

12 dog

13 passage

14 borehole

15 passage

16 passage

17 plug

18 miniature switch

19 switch pin

20 removable element

21 DC gear motor

22 wall

23 toothed roller

24 U-shaped space

25 wall

26 block

27 groove

28 tension slide

30 bolt

31 spiral spring

32 end piece

33 double lever

34 pressure spring

35 axis

36 holder

37 biopsy needle carrier

38 boreholes

40 brackets

41 surface of tension slide

42 extension of surface

43 lower sliding surface

44 surface of block 26

45 recess

46 cover

47 plastic part

48 threaded spindle nut

49 bearing element

50 polygon

51 syringe bottom

52 syringe spindle

53 threaded spindle

54 plunger

55 gear (toothed crown)

56 drive pinion

57 board

58 DC gear motor

29 threaded borehole

60 surfaces

61 free end

62 insert element

63 connector

64 outflow connector

65 recess

66 chamfer

67 ventilation borehole

69 piston/cylinder unit

70 needle tip

71 sample removal chamber

72 cutting edge

73 threaded spindle casing

74 gear

75 threaded spindle nut

76 seal element

77 recesses

78 plastic disk

79 stopper

80 knurled disk

81 guide roller

82 recess

83 metal part

84 safety tab

85 end surface

87 center rib

59 transverse plate

90 cocking button

91 reset diode

92 sample removal diode

93 ejection diode

94 cocking diode

95 locking diode

96 battery charge diode

97 passage

98 passage

99 arm of the double-arm lever

100 part of the lever

101 flanks of the guide roller left

102 flanks of the guide roller right

103 position finger

104 axis

105 actuating device (vacuum)

106 actuating device (biopsy needle, cocking mechanism)

107 recesses

108 brackets

109 cross piece

110 pin

111 storage battery

112 plastic part

113 surface

114 separating plate

115 guide borehole

116 fastening

117 holding pieces

88 activating button

89 program button

119 notch

120 edge of needle carrier

121 tube

122 cap

123 seal element

124 spike

125 coaxial cannula

126 tip

127 screw cap

128 end surface

129 spacing piece

L=length of spacing piece

## ATTACHMENT 2

A mark-up copy of the amendments made in Attachment 1 is provided in this Attachment 2.

Below are the amendments made to paragraphs [0001], [0007], [0016], [0019], [0022], [0027]-[0028], [0033], [0035]-[0036], [0063], [0070]-[0072], [0074], [0080], [0085], [0088], [0092], [0096]-[0097], [00101], and [00103]-[00108]:

**[0001]** This is a national stage application under 35 USC § 371 of International Application PCT/DE03/00844, filed on March 17, 2003, ~~the entire contents of which are incorporated by reference herein~~ which claims priority to DE20204363.0, filed March 19, 2002, DE20204362.2, filed March 19, 2002, DE20204361.4, filed March 19, 2002, DE10212156.7, filed March 19, 2002, DE10212139.7, filed March 19, 2002, DE10212155.9, filed March 19, 2002, DE20209525.8, filed June 19, 2002, DE20209530.4, filed June 19, 2002, DE20211934.3, filed August 2, 2002, and DE20215962.0, filed October 17, 2002, the entireties of which are hereby incorporated by reference.

**[0007]** On the other hand, the biopsy needle arrangement described in International Publication No. WO 98/25522 enables a spring-operated relative motion between the hollow biopsy needle, located on the interior, and the outer hollow needle surrounding the biopsy needle. In this case as well, the biopsy needle is positioned distally to the sharpened distal tip of the hollow needle in order to take a sample, there being provided a partial vacuum source for supplying a partial vacuum through the hollow biopsy needle into the area of its recess, assisting the process of bringing in the tissue. The process of positioning the biopsy needle relatively and finally inside the region of tissue being investigated is done exclusively manually. Such a positioning leads only to unsatisfactory biopsy results, especially when investigating hard tissue regions.

**[0016]** The locking of the tension slide has a double-arm lever, whose one arm engages under spring pressure with the recess of the tension slide. In order to allow for use of the tension device for different biopsy needles with different insertion ~~depth~~ depths, *e.g.*, 15 to 25 mm, it is only necessary to adapt the length of the engaging lever and use appropriate settings in the

electronics, for example. The plastic piece joined to the biopsy needle enables a turning of the sample removal chamber by means of a knurled disk. The biopsy needle can be locked in the desired position by the interaction of the polygon of the plastic piece and the biopsy needle carrier. A notch made in the knurled disk shows the user the radial position for the opening of the sample removal chamber.

**[0019]** The storing of the biopsy needle/cutting sheath in a biopsy needle carrier made of plastic has the advantage, among others, that the molded-on sliding surfaces enable a trouble-free sliding on the opposing surfaces of the base block and the molded-on block. The biopsy needle carrier transmits the forces from the spindle drive of the cutting sheath to the tension slide. Since the spindle drive thrusts against the holder of the base block when the tension slide changes position and it can slide freely when the tension sheath is rotated (the gear can slide axially in the toothed roller), the drive unit can be used for both motion sequences (tensioning of the tension slide, opening and closing of the sample removal chamber by means of the cutting sheath). The miniature switch integrated in the housing end piece, which turns the power supply off and on by the closing of the housing cover with the vacuum pressure-generating device inserted, as well as the retaining tabs arranged on the biopsy ~~needed~~ needle carrier, are safety mechanisms which prevent a tensioning of the tension slide when the housing cover is open. Furthermore, an opening of the housing cover when the needle is under tension will be precluded.

**[0022]** When using a coaxial cannula in which the needle unit is inserted, so as to achieve an exact positioning, for example, one must make sure that no air can get in between the outer circumference of the needle and the inside of the coaxial cannula when a vacuum is produced. Therefore, a seal element is provided at the proximal side of the coaxial cannula tube. Since the depth of insertion of the needle unit is dictated by the cocking distance of the tension slide, unless means are provided in the hand piece for different depths of insertion, the use of spacing pieces between the coaxial cannula and guide roller has proven to be especially advantageous. The spacing piece is strung onto the needle unit and sits distally on the proximal end of the coaxial cannula, and proximally on a guide roller arranged in the hand piece. As a result, for the same insertion length dictated by the device, the depth of penetration is reduced by the length of the spacing piece, resulting in easier production conditions.

**[0027]** Figure 4 shows a cross section ~~B-B in Figure 1~~ A-A in Figure 3 (left housing part).

**[0028]** Figure 5 shows a cross section ~~C-C in Figure 1~~ B-B in Figure 3 (right housing part).

**[0033]** Figure 9a shows a ~~housing-fixed units~~ unit of the biopsy device that is fixed to the housing (without housing cover or bottom) in the uncocked condition.

**[0035]** Figure 10a is the same as Figure ~~9~~9a, but tension slide in cocked position.

**[0036]** Figure 10b is the same as Figure ~~9a~~9b, but in locked condition.

**[0063]** The cocking device (situated right front) itself consists of a tension slide 28, placed on a bolt 30, the bolt screwing into the base block 8. The bolt 30 has a spiral spring 31 surrounding it. The locking device (see especially ~~Figure~~ Figures 9b and 10b) of the tension slide is secured to the block 26. In the top, rear, right interior of the housing is accommodated the vacuum pressure-generating device 5 with parts of the actuator; the actuating motor with reduction gearing for the vacuum pressure-generating device is located in the left, bottom, rear area of the housing interior.

**[0070]** A perspective representation of the base block 8 (looking from the front in the direction of the X-axis) is shown by Figure 8a; the base block 8 is shown from the rear in the X-axis by Figure 8b (both of them perspective views). The base block 8 can be divided into two halves, looking in the lengthwise direction; the front part serves to secure the joint actuation for cutting the sheath and tension slide, and also in its upper part to mount the biopsy needle carrier (Figure 8a); the rear part serves to secure the actuation for the vacuum pressure-generating device and to mount one side of the vacuum pressure-generating device (Figure 8b). Between the two actuating motors 21, 58, beneath the center rib 87, is arranged a central electronic board. The base block 8 has in its left front part a U-shaped space 24, in which is installed a toothed roller 23, driven by the gear motor 21. For this, the take-off shaft of the gear motor is mounted or inserted in an opening in the wall 25 of the base block 8. The toothed roller 23 is mounted on the take-off shaft and secured to it, for example, by means of a screw, so that it cannot turn or shift. At the other end, the toothed roller 23 is mounted in the wall 22 of the base block 8. The actuating motor used is a DC motor with a speed of around 11000 rpm. The DC motor is connected to a planet gear with high reduction ratio, on whose take-off shaft the toothed roller 23 is mounted.

**[0071]** An additional block 26 is molded on the wall 22, pointing to the right, which accommodates both the swiveling double lever 33 for the locking process and also serves to

fasten the bolt 30 for guiding the tension slide 28. The bolt 30 is screwed into the threaded borehole 29. During the cocking process, the tension slide 28 moves to the right on the bolt 30 and the separating plate 114 is arranged underneath. The spiral spring 31 arranged on the threaded bolt 30 is compressed during the cocking process. At one end, the spiral spring thrusts against an end piece 32 of the threaded bolt or directly against the end cover 7 of the housing; the other end of the spiral spring thrusts against the end of the guide borehole 115 of the tension slide.

**[0072]** The tension slide 28 moves on the threaded bolt and the separating plate 114 and is thus prevented from twisting. One arm 99 of the double-arm lever 33 of the locking device engages with a groove 27 of the tension slide 28 (~~Figure~~ Figures 9a and 10a). The locking device, integrated in the block 26 of the base block 8, consists of the double-arm lever 33, which can swivel about an upright axis 35 (looking in the Y-axis) by means of a compression spring 34. The axis 35, an upright pin, is secured in the boreholes 38 of the base block. In the uncocked condition, the part 99 of the double-arm lever lies in the groove 27 of the tension slide; the compressed spring 34 acts on the part 100 of the lever to press the locking button 88 outward (forward). As soon as the part 99 of the double-arm lever can engage in the recess 82 of the tension slide, the activating button 88 is pressed outward. The tension slide is locked by the locking of the lever part 99 in the cocked condition and can now be triggered when necessary with the activating button 88. Since the tension slide is advisedly made of plastic, it has proven advisable to employ a metal part 83 in the recess, so as not to damage the plastic, since the double-arm lever is made of metal. Unlike the removable element 20, the hand piece 1 with replaced insertion element can be used repeatedly. The cocking distance corresponds to the depth of penetration of the biopsy needle into the tissue. Hence, the length of the lever 99 likewise corresponds to the cocking distance. Since the depth of penetration is generally between 15 and 25 mm, the same hand piece 1 can be used for different depth of penetration by appropriately configuring the length of the lever 99 and changing the setpoints of the control system.

**[0074]** Above the U-shaped space 24 for the toothed roller 23, at the height of the sliding surface 42, the basic block 8 has a U-shaped upwardly open holder 36, for inserting the biopsy needle/cutting sheath among other things. This holder serves primarily as a radial thrust bearing, i.e., as a prop for the actuating part connected to the cutting sheath, the gear 74, or the plastic

disk 78, in order to bring the tension slide into its cocked position by means of the actuating device 106, as shall be described afterwards. In the upper rear part of the base block there is provided another U-shaped insert element 62, in which the free end 61 of the threaded spindle of the vacuum pressure-generating device 5, ~~protruding from the syringe body,~~ is inserted. In the middle, top, of the base block 8 is~~, there is a fastening for a plate, which accommodates~~ the recess 45, into which the dog 12 of the locking latch 11 of the housing cover is forced. A cover 46 arranged on the base block 8, pointing to the left, separates the space of the actuating motors and the board from the upper left part of the housing interior, which is used primarily to keep the exchangeable biopsy needle carrier 37, including biopsy needle and cutting sheath. The cover 46 protects the electric gear motors and the board against dirt. The board for the electronics lies between the actuating motors and underneath the middle rib.

**[0080]** Details of the sample removal chamber and the tip of the biopsy needle are represented in ~~Figure~~ Figures 11a-11e. The sample removal chamber 71 adjoining the needle tip 70 is open from above for approximately 25% of its cross section. The cutting edges can be ground or sharpened. The sample removal chamber is between approximately 15 and 25 mm in length. It adjoins the cavity of the biopsy needle. At the transition, ie., the right end of the sample removal chamber, the cross section of the cavity of the biopsy needle is closed between approximately 50% and 75% by a narrowing, e.g., a stopper 79 (~~Figure~~ Figures 11b-11e). The height of the stopper is chosen such that it extends downward past the recess of the sample removal chamber. In this way, the vacuum will especially draw in the tissue sample through the continuous opening of the sample removal chamber and bring the tissue sample up against the wall of the sample removal chamber.

**[0085]** The plunger 54 is configured in familiar fashion as a syringe plunger. The syringe body made from plastic, being a cylinder with a bottom, is transparent. In order to prevent a twisting of the threaded spindle 53 upon actuation of the threaded spindle nut, the two opposite surfaces 60 of the threaded spindle are ~~plane~~ planar in configuration (Figure 14d). The threaded spindle is inserted into the insert element by its free end. The spacing between the surfaces of the threaded spindle corresponds to the width of the U-shaped insert element 62 of the base block 8. There is only slight play between the U-shaped cross section of the insert element and the spindle surfaces at either end. The threaded spindle nut thrusts against the base block. In order to prevent the syringe body 52 from sliding out upon turning of the threaded spindle nut, the

bearing surface at the base block 8 is slightly conical toward the bottom. The connection piece 63 of the syringe body 52 is inserted into the passage 16 of the right end cover 7 so that the syringe body is held in roughly horizontal position.

**[0088]** The handling of the biopsy mechanism shall now be explained more ~~fully:~~ fully. The removable insert element 20, comprising a vacuum pressure-generating device, elastic connection element, biopsy needle carrier with needle and cutting sheath and additional elements connected to it, also contains a guide roller 81 mounted on the needle. This unit, including an insert aid, comes in a sterile package. The plunger 54 in the syringe body 52 comes slightly (1-2 mm) lifted up from the syringe bottom, the sample removal chamber 71 of the biopsy needle 2 is open so that one can make a visual inspection of the chamber prior to inserting. After opening the housing cover 10, the carrier element 37, including biopsy needle 2, cutting mechanism 3, and other parts connected with it, such as the vacuum pressure-generating device 5 hooked up to the connection element 4, is inserted into the connection element provided for this (Figure 2).

**[0092]** After the starting positions are reached for the vacuum pressure-generating device and the biopsy needle/cutting sheath, the cocking diode 94 and the sample removal diode 92 light up green, and the reset diode goes out. The operator must now decide whether to initiate the cocking of the tension slide or to remove an additional sample, e.g., because he has already previously removed one tissue sample. If the operator presses the cocking button 90, the cocking of the tension slide is initiated; the cocking diode blinks green, the sample removal diode 92 goes out. By pressing the cocking button, the electrical DC gear motor 21 receives current and the DC gear motor actuates the toothed roller 23. The gear 74 meshing with the toothed roller 23 turns the spindle shaft and at the same time the cutting sheath 3 connected to it. Since the spindle nut 75 is press-fitted in the biopsy needle carrier 37 and the gear 74 is supported by the plastic disk 78 against the holder 36, which is firmly connected to the housing by the base block 8, the turning of the threaded spindle casing 73 has the effect of moving the biopsy needle carrier to the right.

**[0096]** It has proven to be advantageous to direct the partial vacuum by the stopper 79 primarily at the lower region, the lower side, of the sample removal chamber, and the stopper 79 will prevent or impede tissue from getting into the biopsy hollow needle. When the sample removal chamber is fully open--the tissue sample is accommodated in the sample removal chamber--the gear motor 21 is reversed and the sample removal chamber ~~39~~ is closed. By

turning the cutting sheath, the tissue is separated by the cutting edge 72 of the sheath 3 during the closing process. In order to reliably cut through the tissue filaments, it is advantageous to move the cutting sheath 3 beyond the distal end of the sample removal chamber (around 2 mm). In order to accomplish this, it is only necessary to program accordingly the microprocessor where the control data is kept. Because of the special configuration of the sample removal chamber and thanks to the vacuum applied, the tissue sample is held in the chamber without torsion, so that the tissue sample is not twisted or turned by the rotating and lengthwise moveable cutting sheath 3 which surrounds the biopsy needle on the outside, as described.

**[0097]** After the sample removal chamber is closed, the DC gear motor is activated for the vacuum generating unit 5. The plunger 54 is first retracted far enough to clear the ventilation opening (~~Figure 11e~~Figure 14c). After the vacuum is dissipated in the system, the plunger travels toward the vacuum bottom until the ventilation borehole is again closed, in order to prevent the outflow of bodily fluid (cytological fluid). The blinking of the sample removal diode 92 goes out. The ejection diode 93 lights up green. The biopsy needle with closed sample chamber is extracted from the cannula. After the removal of the biopsy unit and providing a vessel to receive the tissue sample and fluid, the program button 89 is again operated and the ejection diode 93 starts to blink. At first, the gear motor 21 of the cutting sheath is operated to open the sample removal chamber roughly halfway. After this, the DC gear motor 58 of the vacuum pressure-generating device is activated. The turning direction of the DC gear motor 58 remains and the threaded spindle 53 with plunger moves in the direction of the syringe bottom, so that now an excess pressure is created in the system. The plunger travels up to the plunger bottom, and the actuating motor 58 is deactivated.

**[00101]** After completion of the biopsy, the interchangeable element 20 (vacuum/pressure device, biopsy needle/cutting device with all elements arranged on it) is removed from the top after releasing the cover. To make it impossible to open the housing when the tension slide is cocked, a safety tab 84 is arranged on the biopsy needle carrier, which bears against the left end surface 85 of the closure mechanism in the cocked condition. In this way, the closure mechanism, moveable in the X-axis, can no longer be moved to the left into the open position and thus the dog 12 can no longer be taken out from the recess 45. On the other hand, the housing cover also cannot be closed if the carrier unit has been inserted in the cocked condition, since the safety tab prevents the latch from being introduced into its designated space.

The surface 85 of the latch adjoins the safety tab. The battery charge diode 96 is turned off as soon as the housing cover is ~~open~~ opened. When the cover is closed and the insert element 20 is installed, the battery charge diode indicates whether sufficient energy is available.

**[00103]** Basically, there are two conceivable methods for detecting the actual values and comparing them to the nominal values. One method is based on measuring the lengthwise displacement of the threaded spindle as it is pulled out or pushed in, and measuring the axial displacement of the cutting sheath or the biopsy needle carrier. In order to detect these changes, photocells or miniature switches are arranged inside the housing, in particular on the extension of the base block 8. In addition, a positioning finger 103 is mounted on the cutting sheath, while the free end 61 protruding from the plunger unit can be used as a measuring point for the threaded spindle of the vacuum pressure-generating device; if the front edge of the biopsy needle carrier is used as a measuring point with a photocell, no additional positioning finger is required. The embedded photocells are covered with suitable transparent material in case of possible contamination. The positioning finger 103 engages with a slot in the biopsy needle holder. At appropriate places on the extension ~~46~~ of the base block 8 there are provided recesses 107, in which photocells or miniature switches are installed, which interact either with the free end 61 of the plunger spindle, ~~with the position finger~~ the positioning finger 103, or ~~the~~ an edge of the biopsy needle carrier ~~120~~ (see Figure 15). These signals (actual value) are processed in the electronics to form the control signals.

**[00104]** The other system is based on measuring the number of revolutions of the DC motors. In this case, a pickup is mounted on the shaft of the DC motor, which interacts with a photocell mounted on the housing of the DC motor. In this way, the number of revolutions of the motor is measured. Since the DC motors operate with a speed of around 10,000 to 12,000 rpm, depending on the load, and on the other hand the secondary planet transmission arranged at the take-off end which interacts with the spindle drive considerably reduces the number of revolutions, an exact lengthwise control is possible. The lengthwise displacement by the spindle drive is a constant value proportional to the operating speed and is therefore sufficient as a control signal for the lengthwise displacement. In order to precisely determine the position of the cutting sheath 3 as well as the plunger 54 at the start, i.e., after inserting the removable element and closing the housing cover 10, the DC gear motor 58 rotates the plunger 54 until it strikes against the syringe bottom and the DC gear motor 21 brings the drive of the cutting

sheath to ~~the~~ a zero position by moving the gear 74 until it strikes against the threaded spindle nut 75. (The threaded spindle nut 75 ~~strikes~~ abuts against the gear 74.) From this zero position, the individual steps are then controlled by comparing the settings and the actual values. The necessary cables from the measuring pickup to the electronics are accommodated in the housing, as is the board with the electronic components. A microprocessor arranged inside the housing, under the cover, with the setpoint values stored in it, controls the individual processes.

**[00105]** In order to enable easy insertion of the removable insert unit, the insert aid shown in ~~Figure 16, 17~~ Figures 16 and 17 can be used. As ~~Figure 16, 17~~ Figures 16 and 17 show in particular, the biopsy needle carrier is enclosed by two brackets 108 and axially fixed in the holder by an additional cross piece 109, so that it comes to lie parallel to the vacuum/pressure device in the insert aid. The vacuum pressure-generating device is likewise enclosed by the bracket 116 at one side and by the centrally arranged bracket 108 on the other side. In addition, a pin 110 engages with the ventilation borehole 67. This ensures that the vacuum pressure-generating device is oriented parallel to the biopsy needle carrier (Figure 1). The parts so oriented are fixed in the insert aid so that they can easily be inserted from above into the hand piece 1 by means of the holder piece 117. Since the parts come in a sterile package with the insert aid, the interchangeable element 20 can be removed from the package without manual contact and be inserted in ~~sterile~~ a sterile manner into the hand piece 1. The brackets are slightly slanted for easier lodging of the vacuum pressure-generating device and the biopsy needle carrier. Since the insert aid is made of plastic, the installed parts can easily be held in place by clamping, thanks to appropriate choice of the tolerance and flexibility.

**[00106]** The tip of the needle unit of the biopsy device can be placed directly on the tissue being sampled and inserted into the tissue. It can be expedient, however, to first position a coaxial cannula and then introduce the portion of the needle unit (consisting of biopsy needle and cutting sheath) protruding from the hand piece I of the biopsy device into the coaxial cannula 125. In this case, one should make sure that, when the vacuum is created for sucking in the tissue sample, no air can get in from the outside into the space between the inner surface of the coaxial cannula and the outer surface of the needle unit. In the coaxial cannula (Figure 18) consisting of a tube 121 with cap 122 placed at the proximal end, the tube 121 at the proximal end has a seal element 123 (e.g., a properly dimensioned silicone hose), into which the needle unit is placed. In order to insert the coaxial cannula, a spike 124 is connected to the coaxial

cannula 125. The spike 124 has a tip 126 protruding beyond the distal end of the coaxial cannula in the inserting state. The connection between coaxial cannula and spike is a screw fastening, for example, so that the spike cap is configured as a screw cap 127. The screw cap is screwed onto the proximal end of the cap 122. The tube of the coaxial cannula is held in the cap 122 by clamping, for example. After inserting the coaxial cannula, the spike is removed and the needle unit of the biopsy device (in the cocked condition) is introduced and positioned in the coaxial cannula (Figure 20). The distal flank 101 of the guide roller ~~101~~ is placed on the proximal end surface 128 of the cap. After the tension slide is released, the needle tip with the sample removal chamber is forced into the tissue to its full length.

**[00107]** The depth of penetration of the biopsy needle unit of the biopsy device is between 20 and 35 mm, depending on the selected size of needle. In general, it is 20 mm. In the case of small breasts or tumors lying just below the skin, the depth of penetration of the biopsy needle is therefore too deep, since the biopsy device is placed directly or by means of the guide roller onto the coaxial cannula and the depth of penetration cannot be changed at the device. The depth of penetration is device-fixed. In order to be able to use the same biopsy device with the same biopsy needle and same depth of insertion and the same, i.e., uniform coaxial cannula with same overall length and less depth of insertion, one or more spacing pieces 129 are placed medially onto the biopsy needle prior to insertion; thus, these lie medially in front of the guide roller ~~101~~ mounted in the housing and the proximal end surface 128 of the cap 122. Thus, by introducing spacing pieces or a spacing piece, the depth of penetration ~~T~~ can be changed for the same depth of insertion provided in the device.

**[00108]** After inserting the spacing piece, the tip of the biopsy needle in the cocked condition no longer projects slightly from the coaxial cannula, as when no spacing piece is used, but rather lies in the coaxial cannula. The depth of penetration is thus reduced by the length L of the spacing piece (also see ~~Figure~~ Figures 20 and 21). This does not impair the functioning of the sample removal chamber ~~21~~ or the operation of the cutting sheath. For example, if a spacing piece of 10 mm is used with a depth of needle penetration of 20 mm, the depth of penetration will be reduced to 10 mm. Of course, the spacing piece can be made up of one or more parts, i.e., when using spacing pieces of 5 mm thickness, two spacing pieces are necessary to reduce the depth of penetration by 10 mm. The adding of spacing pieces or one spacing piece of corresponding length offers the possibility of using a uniform coaxial cannula including a

uniformly added insertion spike 124 for various depths of penetration. The same result regarding a reduced depth of penetration could also be achieved by using caps of different height or by mounting the spacing pieces on the cap, which is equivalent to the threaded-on spacing pieces.

Below are the amendments made to the section entitled "List of parts" beginning at page 35:

List of parts

1 hand piece

2 biopsy needle

3 cutting sheath

4 connection element

5 vacuum pressure-generating device

6 housing end cover (left)

7 housing end cover (right)

8 base block

9 housing lower piece

10 housing cover

11 locking latch

12 dog

13 passage

14 borehole

15 passage

16 passage

17 plug

18 miniature switch

19 switch pin

20 removable element

21 DC gear motor

22 wall

23 toothed roller

24 U-shaped space

25 wall

26 block

27 groove

28 tension slide

30 bolt

31 spiral spring

32 end piece

33 double lever

34 pressure spring

35 axis

36 holder

37 biopsy needle carrier

38 boreholes

~~39 not used~~

40 brackets

41 surface of tension slide

42 extension of surface

43 lower sliding surface

44 surface of block 26

45 recess

46 cover

47 plastic part

48 threaded spindle nut

49 bearing element

50 polygon

51 syringe bottom

52 syringe spindle

53 threaded spindle

54 plunger

55 gear (toothed crown)

56 drive pinion

57 board

58 DC gear motor

29 threaded borehole

60 surfaces

61 free end

62 insert element

63 connector

64 outflow connector

65 recess

66 chamfer

67 ventilation borehole

~~68 not used~~

69 piston/cylinder unit

70 needle tip

71 sample removal chamber

72 cutting edge

73 threaded spindle casing

74 gear

75 threaded spindle nut

76 seal element

77 recesses

78 plastic disk

79 stopper

80 knurled disk

81 guide roller

82 recess

83 metal part

84 safety tab

85 end surface

~~86 not used~~

87 center rib

59 transverse plate

90 cocking button

91 reset diode

92 sample removal diode

93 ejection diode

94 cocking diode

95 locking diode

96 battery charge diode

97 passage

98 passage

99 arm of the double-arm lever

100 part of the lever

101 flanks of the guide roller left

102 flanks of the guide roller right

103 position finger

104 axis

105 actuating device (vacuum)

106 actuating device (biopsy needle, cocking mechanism)

107 recesses

108 brackets

109 cross piece

110 pin

111 storage battery

112 plastic part

113 surface

114 separating plate

115 guide borehole

116 fastening

117 holding pieces

88 activating button

89 program button

~~118 not used~~

119 notch

120 edge of needle carrier

121 tube

122 cap

123 seal element

124 spike

125 coaxial cannula

126 tip

127 screw cap

128 end surface

129 spacing piece

~~T=depth of penetration~~

L=length of spacing piece